

REMARKS

Claims 1-7, 9-17, 19-28, 30-38, 40-49, 51-59 and 61-65 remain pending in this application. Claims 8, 18, 29, 39, 50 and 60 have been cancelled.

Response To Objection To Specification

Reconsideration and withdrawal of the objection of record is respectfully requested in view of the remarks contained herein.

Item # 4. The Examiner states that the “specification is objected because of . . . [t]he use of the trademark Puregene,” and further states that “[i]t should be capitalized wherever it appears and be accompanied by generic terminology.”

It is respectfully pointed out to the Examiner that the trademark Puregene® has been capitalized wherever it appears in the specification to PUREGENE®, and accompanied by generic terminology w.r.t. the known composition of each reagent.

Response To Rejections

The applicant thanks the Examiner for favorably considering the arguments and amendment with respect to the prior art formerly cited.

Reconsideration and withdrawal of the rejections of record is respectfully requested in view of the remarks contained herein.

35 U.S.C. § 112

Item 5. The Examiner states that “[c]laims 2-7, 9-17, 19-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.” With respect to claims 9-12, 30-33, 51-54 whose metes and bounds the Examiner states are unclear because” the hypertonic, high-salt reagent recited in the independent claims 1-2, 24 and 45 describe

that the reagent is to form a suspension, however the dependent claims 9-12, 30-33, 51-54 recite that reagent “precipitate protein out of the lysate, which makes the claims indefinite, because it is not clear whether the reagent is used for making a suspension of biological material or used to lyse the biological material as lysis reagent.”

It is respectfully pointed out to the Examiner, that claim 2 has been amended as per the advice of the Examiner such that claim 2 now recites the limitation “the suspension of step(a)” in step(b) of the claim, so as to recite proper dependency. It is also pointed out to the Examiner that the term “physically” has been deleted in claims 12-20, 40-41, 61-62 as per the advice of the Examiner to obviate the Examiner’s rejection.

With respect to claims 9-12, 30-33, 51-54, it is respectfully pointed out to the Examiner that claims 9-12, 30-33, 51-54 have been amended to obviate the Examiner’s rejection. Specifically, the claims have been amended to recite that the hypertonic, high-salt reagent comprises salt in an amount effective to precipitate contaminating proteins out of the biological sample. Support for this amendment can be found in the specification at page 16, lines 7-14.

35 U.S.C. § 102

Item 6. The Examiner states that “[c]laims 1-2, 4, 7, 9-16, 19-24, 28, 30-37, 40-44 are rejected under 35 U.S.C. 102(b) as being anticipated under Younghusband et al.”

It is respectfully pointed out to the Examiner that the invention claims a method involving fewer steps than DNA isolation methods existing in the prior art which makes both unique and advantageous. Thus, the method of the invention as recited in claims 1-2, 4, 7, 9-16, 19-24, 28, 30-37, 40-44 involve the following sequential steps: (i) contacting the biological material comprising DNA with a hypertonic, high salt reagent so as to form a suspension of said biological material containing DNA; and (ii) contacting the suspension created in this prior step with a lysis reagent so as to lyse the biological material containing DNA to form a lysate comprising DNA and non-DNA biological components released from

the biological material. The term sequential in respected dictionaries is defined as: “following; subsequent; consequent.” The term sequential does not imply that there are intervening steps in between two sequential steps; it means that the steps as recited are followed one after another. As stated in the specification on page 7, lines 19-20, “[t]he invention of the current method allows the cells to be directly suspended in a hypertonic, high-salt reagent, followed by the addition of a lysis reagent.” Moreover, as described on page 20, lines 12-14, “[i]mmmediately following this step [suspension of cells in the hypotonic, high-salt solution], a volume of 10 ml cell lysis solution . . . was added to the sample to lyse the cells.” Moreover, the method of the invention teaches that the cell lysis solution is sequentially added to the suspension of cells.

In contrast, Younghusband teaches a method in which the cells are pre-lysed, the nuclei separated and then suspended in a high salt reagent, incubated for 30 minutes at 37 °C, then layered over a solution of 15% glycerol and other components., centrifuged for 45 minutes, and then resuspended in a solution containing 3% SDS. The step in which the biological material containing DNA is contacted with the hypotonic, high-salt reagent, and the addition of the lysis solution to the solution of biological material in the hypotonic, high-salt reagent do not sequentially follow each other, but involve at least three intervening steps. Moreover, the lysis reagent in Younghusband is not added to the suspension of biological material in the hypotonic, high-salt reagent, but is added to a pellet created by several intervening steps.

It is an objective of this method involving the aforementioned sequential steps to “reduce the number of steps.” See page 16, lines 17-19. This objective is stated numerous times in the specification and the method of the invention compared with a standard DNA isolation method in Example 1 of the specification on pages 17-20. A method such as the one taught in Younghusband, however, involves numerous steps that the method of the invention seeks to avoid, and as such, the objective of the invention was a method unique and distinct from existing methods such as that taught by Younghusband.

The Examiner is requested to consider the aforementioned argument distinguishing the method of the present invention over Younghusband that shows that Younghusband does not meet the limitations of the instant claims.

35 U.S.C. § 103

Item 7. The Examiner states that “[c]laims 3-6, 17, 25-27, 38, 45-49, 51-59, 61-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Younghusband et al. . . . in view of Gray et al. . . .”

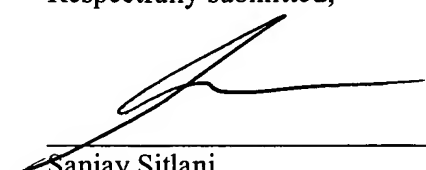
As pointed out to the Examiner in the aforementioned argument with respect to Younghusband, Younghusband does not meet the limitations of the instant claims and that the method of the claimed invention is distinct and unique over Younghusband. Thus, the combined references of Younghusband and Gray do not recite the teachings of the instant invention.

Based on the remarks above, applicant believes all pending claims are in condition for allowance.

If the Examiner believes that a conference would be of value in expediting the prosecution of this application, the Examiner is hereby invited to telephone undersigned counsel to arrange for such a conference.

Respectfully submitted,

September 19, 2006
Date



Sanjay Sitlani
Registration No: 48,489
Attorney for Applicants
Customer No. 26633

Heller Ehrman LLP
1717 Rhode Island Avenue, NW
Washington, D.C. 20036
(202) 912-2000 (phone)
(202) 912-2020 (fax)